

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
Tyler Division

MAGELLAN TECHNOLOGY, INC.;)	
2225 Kenmore Avenue, Suite 110)	
Buffalo, New York 14207,)	
)	
and)	
)	
VAPOR TRAIN 2 LLC;)	
3500 McCann Road)	
Longview, Texas 75605,)	
)	
Plaintiffs,)	
)	Case No.
v.)	
)	
U.S. FOOD AND DRUG ADMINISTRATION;)	
ROBERT M. CALIFF, M.D., Commissioner for)	
Food and Drugs;)	
10903 New Hampshire Avenue)	
Silver Spring, Maryland 20903,)	
)	
U.S. DEPARTMENT OF HEALTH AND)	
HUMAN SERVICES;)	
XAVIER BECERRA, Secretary of Health and)	
Human Services;)	
200 Independence Avenue, S.W.)	
Washington, D.C. 20201,)	
)	
Defendants.)	

VERIFIED COMPLAINT
(TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION
REQUESTED)

Plaintiffs Magellan Technology, Inc. (“Magellan”) and Vapor Train 2 LLC (“Vapor Train”), for their Verified Complaint against the United States Food and Drug Administration, Robert M. Califf, M.D., Commissioner for Food and Drugs (collectively, “FDA”), the United States Department of Health and Human Services, and Xavier Becerra, Secretary of the Department of Health and Human Services (collectively, “HHS”), hereby state as follows:

NATURE OF THE ACTION

1. Through this action, Plaintiffs seek a declaratory judgment that FDA has violated the Administrative Procedure Act by issuing a Refuse to Accept (“RTA”) order for twelve bundled Premarket Tobacco Product Applications (“PMTAs”) that Magellan submitted for various electronic nicotine delivery system products it markets.

2. Plaintiffs contend that FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the RTA order because the agency (i) invoked regulations governing PMTA acceptance that do not apply to Magellan’s PMTA and (ii) failed to consider timely amendments containing required content that Magellan properly submitted but which FDA failed to link to the corresponding applications because of its own failure to issue Submission Tracking Numbers (“STNs”) to Magellan for the underlying applications.

3. Plaintiffs seek (i) a temporary restraining order and preliminary injunction staying the RTA order pending the outcome of this action; and (ii) a final judgment setting aside the RTA order and remanding to FDA for further review of Magellan’s PMTAs.

THE PARTIES

4. Plaintiff Magellan Technology, Inc., is a corporation headquartered in Buffalo, New York. Magellan distributes ENDS products nationwide, including in this district. Magellan is the master distributor of all Hyde- and JUNO-branded ENDS products. Through its scientific advisors, on May 12 and 13, 2022, Magellan submitted twelve bundled applications for marketing authorization for a range of Hyde- and JUNO-branded ENDS products to FDA.

5. Plaintiff Vapor Train 2 LLC is a Texas limited liability company headquartered and with two retail stores in Longview, Texas. Until FDA issued the RTA order, Vapor Train

purchased Hyde-branded ENDS products from Magellan and sold them to consumers at retail through its two stores.

6. Defendant United States Food and Drug Administration is a division of Defendant Department of Health and Human Services (“HHS”). The headquarters and principal place of business of FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20903. The headquarters and principal place of business of HHS is 200 Independence Avenue, S.W., Washington, D.C. 20201. Defendant Robert M. Califf, M.D., is the Commissioner of the Food and Drug Administration and is sued in his official capacity. Defendant Xavier Becerra is the Secretary of Health and Human Services and is sued in his official capacity.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331. This Court has the authority to grant the declaratory relief requested by Plaintiffs pursuant to 28 U.S.C. §§ 2201 and 2202. The Court also has the authority to hold unlawful and set aside FDA’s actions pursuant to 5 U.S.C. §§ 702 and 706 and to grant temporary and preliminary injunctive relief pursuant to 5 U.S.C. § 705.

8. This Court has personal jurisdiction over Defendants FDA, HHS, Commissioner Califf, and Secretary Becerra in their official capacities, as each is an agency or official of the United States Government.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) as the district wherein Plaintiff Vapor Train 2 LLC resides.

FACTS

A. ENDS Products are “Tobacco Products” under the Tobacco Control Act

10. Electronic nicotine delivery system (“ENDS”) products are regulated by FDA as “tobacco products” under the Tobacco Control Act (“TCA”), 21 U.S.C. §§ 387, *et seq.*, because they “contain[] nicotine from any source” and are “intended for human consumption.” 21 U.S.C. § 321(rr)(1). As such, they are subject to the requirements of Subchapter IX of the Federal Food, Drug and Cosmetic Act (“FDCA”).

11. Section 910 of the FDCA, 21 U.S.C. § 387j, requires that any tobacco product that was not commercially marketed as of February 15, 2007, receive a marketing order from FDA prior to being commercially marketed in the United States.

12. Prior to April 15, 2022, ENDS products containing nicotine that was synthetically manufactured or otherwise not derived from tobacco plants did not qualify as “tobacco products” and were not subject to Section 910’s premarket authorization requirements because the statutory definition of a “tobacco product” extended only to products “made or derived from tobacco that [are] intended for human consumption, including any component, part, or accessory of a tobacco product.” 21 U.S.C. § 321(rr) (2009). However, the Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, §111(a) expanded the statutory definition to include products containing nicotine “from any source” effective April 15, 2022.

13. As a result, manufacturers and distributors of ENDS products were required to submit premarket tobacco applications for these synthetic nicotine products. If they submitted PMTAs by May 14, 2022, they would not be in violation of the Section 910’s marketing authorization requirement during the 60-day period up through July 13, 2022. *See id.* at § 111(d).

B. FDA has Historically Extended Enforcement Discretion to ENDS Products with Timely Submitted and Pending PMTAs

14. May 14, 2022, was not the first time that manufacturers and distributors of ENDS products were required to submit PMTAs for their products in order to keep them on store shelves.

15. When the Tobacco Control Act was first enacted in 2009, its requirements originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b). The TCA's requirements would only apply to other products meeting the statutory definition of a "tobacco product" if FDA "by regulation deems" such products to be "tobacco products." *Id.*

16. Through its so-called "Deeming Rule," 81 Fed. Reg. 28974 (May 10, 2016) (codified at 21 C.F.R. § 1143.1), FDA deemed ENDS products containing nicotine derived from tobacco plants to be tobacco products.

17. However, because thousands, if not millions, of ENDS products were already commercially marketed in the United States, in the Deeming Rule's preamble, FDA introduced a discretionary enforcement policy that allowed for delayed compliance periods for ENDS products. *See* 81 Fed. Reg. at 29009-15.

18. Under this discretionary enforcement policy, PMTA submissions were originally required to be filed in 24 months, or by August 8, 2018. 81 Fed. Reg. at 28977-78, 29011. Tobacco products, including ENDS products, already on the U.S. market would not be subject to FDA enforcement action in the meantime or while a timely submitted PMTA was pending FDA review. *Id.*

19. FDA's deadline for the filing of PMTAs under its discretionary enforcement policy, however, changed multiple times over the succeeding years, and these changes resulted in

significant litigation. *See Vapor Technology Ass’n v. FDA*, 977 F.3d 496, 497-502 (6th Cir. 2020) (summarizing history of litigation surrounding PMTA submission deadline).

20. Ultimately, to comply with an order from the United States District Court for the District of Maryland,¹ FDA specified that ENDS products for which a PMTA was submitted by September 9, 2020, could continue to be commercially marketed for a period of up to one year after September 9, 2020, provided that the PMTA remained pending and FDA had taken no adverse action on the application.²

21. Even after September 9, 2021, however, FDA has continued to exercise enforcement discretion to allow the continued marketing of ENDS products containing tobacco-derived nicotine for which timely submitted PMTAs are still pending or, in certain cases, where FDA originally issued a marketing denial order on the PMTA, but then either administratively stayed or retracted the marketing denial order. *See, e.g., Turning Point Brands, Inc. v. FDA*, No. 21-3855, ECF No. 19, p. 9-10 (6th Cir. Oct. 8, 2021); *My Vape Order, Inc. v. FDA*, No. 21-71302, ECF No. 45, p. 2 (9th Cir. Dec. 30, 2021); *Juul Labs, Inc. v. FDA*, No. 22-1123, Doc. # 1953737 (D.C. Cir. July 6, 2022).

22. With respect to ENDS products containing non-tobacco-derived nicotine, prior to July 13, 2022, FDA publicly indicated that it would utilize the same approach, with ENDS products that are the subject of pending applications “subject to enforcement at FDA’s discretion.” *See* Nicholas Florko, Stat News, *FDA appears to hold off on crackdown on synthetic nicotine products, despite calls from Congress* (July 8, 2022).

¹ *See* April 22, 2020 Order in *American Academy of Pediatrics v. FDA*, No. 8:18-cv-00883-PWG (D. Md.).

² U.S. Food & Drug Admin., Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised), at 27-28 (Apr. 2020), <https://www.fda.gov/media/133880/download>.

23. To date, to the knowledge of Petitioners, FDA has not issued a Warning Letter to any manufacturer or importer of an ENDS product regarding a product for which a timely filed PMTA remains pending.

C. Regulations and Forms Governing FDA's Premarket Tobacco Product Application Requirements

24. In June 2019, FDA issued its final guidance on PMTAs for ENDS products. FDA, Guidance for Industry, *Premarket Tobacco Applications for Electronic Nicotine Delivery Systems* (June 2019), <https://bit.ly/2XZIEah>.

25. In September 2019, FDA issued a proposed rule governing PMTAs. Premarket Tobacco Product Applications and Recordkeeping Requirements, Proposed Rule, <https://bit.ly/2m5c2g8>.

26. FDA published its final PMTA Rule setting out the requirements for a PMTA and the procedures for FDA's review of such applications in the *Federal Register* on October 4, 2022. Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed. Reg. 55300 (Oct. 4, 2020), <https://bit.ly/3Dt3d57>.

27. In March 2020, FDA included in the reopening of the comment period on the proposed PMTA rule the potential for adding a new Form 4057b to the PMTA submission requirements. *See* 85 Fed. Reg. 13840, 13840-41 (Mar. 10, 2020).

28. The purpose of the form was for submitting PMTAs that contained multiple ENDS products in a single "bundled" submission. *Id.* at 13841.

29. The Office of Management and Budget ("OMB") granted its approval to FDA's inclusion of the amended Form 4057b in its PMTA forms. Office of Management and Budget, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, ICR 202003-0910-008; <https://bit.ly/3f9qcsv>.

30. On April 13, 2022, two days before the expanded definition of “tobacco products” established by the Consolidated Appropriations Act, 2022, took effect, FDA sought emergency authority from OMB to amend Form 4057b, and on April 14, 2022, OMB granted emergency authorization for FDA to use the amended Form 4057b. Office of Management and Budget, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, ICR 202204-0910-012; <https://bit.ly/3sv5YMY>.

31. FDA did not publish the amended Form 4057b on its website where potential applicants could access it until April 28, 2022. FDA, *Premarket Tobacco Product Applications*, <https://bit.ly/3Dapi7h>.

32. FDA failed to publish notice of the amendment in the Federal Register until May 16, 2022, two days *after* the PMTA submission deadline for the newly defined “tobacco products.” 87 Fed. Reg. 29749 (May 16, 2022).

33. FDA’s regulations require that applicants submit their PMTAs electronically. *See* 21 C.F.R. § 1114.49(a). This may be done either through FDA’s Center for Tobacco Products electronic submission portal, or “CTP Portal,” or FDA’s separate agency-wide “Electronic Submissions Gateway,” although FDA’s website recommends submitting PMTAs through the CTP Portal due to better functionality.³

D. Magellan’s PMTAs

34. On May 12 and 13, 2022, Magellan, through its scientific advisors, timely submitted eleven separate bundled PMTAs for Juno and Hyde-branded ENDS products containing non-tobacco-derived nicotine.

³ *See* <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>.

35. Most of the bundled PMTAs were submitted on Magellan's behalf by SKYTE Testing Services Guangdong Co., Ltd. ("SKYTE") through its CTP Portal account.

36. One of the bundled PMTAs was submitted by Magellan's other scientific advisor, Accorto Regulatory Solutions, LLC ("Accorto") through its Electronic Submissions Gateway account.

37. For each of the submissions by SKYTE, the CTP Portal failed to generate a Submission Tracking Number ("STN") for each submission.

38. FDA never issued any correspondence or notice to Magellan providing STNs for the bundled PMTAs submitted by SKYTE through the CTP Portal.

39. It was only after Magellan later received the Refuse to Accept order (discussed in further detail below) on October 6, 2022, that it learned that the STN numbers assigned to the SKYTE bundled applications were PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; and PM0006322.

40. However, for the bundled PMTA Accorto submitted FDA's Electronic Submissions Gateway, the Electronic Submissions Gateway generated an STN after the submission was uploaded, and that PMTA was assigned STN PM0005595.

41. FDA's practice and regulations governing PMTAs allow applicants to submit amendments prior to FDA issuing a refuse to accept order. *See* 21 C.F.R. §§ 1114.9.

42. On August 18, 2022, SKYTE uploaded supplemental amendments for each of the bundled PMTAs it had originally submitted on May 12 and 13, 2022.

43. Because the CTP Portal failed to generate an STN number for each of the original bundled applications, when SKYTE sought to submit amendments for the applications, it did not have an STN that it could list either in the CTP Portal or on the Form 4057a that was part of the

supplemental amendment to identify the original application to which the amendment was to be linked.

44. Despite FDA's CTP Portal failing to provide STNs for Magellan's PMTAs, SKYTE provided identifying information for each of the amendments so FDA could link them to the prior submissions.

45. Like the initial bundled applications themselves, each supplemental amendment submitted on August 18, 2022, identified in the zipped file name itself the particular ENDS device to which the amendment related.

46. The amendments submitted by SKYTE on August 18, 2022, contained a completed Form 4057a, as well as a Form 4057 and a Form 4057b for each of the bundled submissions. The "Submission Summary" section on page 7 of 14 of these Forms 4057a stated that the purpose of the supplemental submissions was to supply Forms 4057 and 4057b for each bundled submission.

47. As part of its PMTAs, Magellan submitted a substantial number of dual language documents provided by the manufacturer of the subject ENDS products that include content in both English and Mandarin Chinese.

48. These dual language documents include documents related to the manufacturer's processes for manufacturing and maintaining quality control over the subject ENDS products, including specifications, protocols, and standard operating procedures.

49. These dual language documents did not result from the translation of original Mandarin Chinese-language documents into English. Rather, they are original dual language documents that are kept and maintained in the ordinary course of business by the manufacturer as a dual language document, not as a document that is only in Mandarin Chinese.

50. The manufacturer maintains these design and production documents in both languages in the normal course of its business specifically because they are for an American customer, Magellan, and the manufacturer knows that they will be required for FDA's review. Indeed, the manufacturer maintains many similar dual language documents for its own branded ENDS products for which it has sought premarket authorization from FDA.

E. FDA's Refuse to Accept Order

51. On October 6, 2022, FDA issued a Refuse to Accept order to Magellan for its ENDS products in the bundled PMTAs assigned STNs: PM0005337; PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; PM0006322; and PM0005595. A copy of the RTA order with confidential manufacturer information redacted is attached hereto as **Exhibit A**.

52. The RTA order was the first notice Magellan received from FDA regarding any purported deficiency in any of its bundled PMTAs.

53. For each of the PMTAs submitted by SKYTE, FDA determined that the submissions failed to include FDA Form 4057b–Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 C.F.R. § 1105.10(a)(6) and 21 C.F.R. § 1114.7(b).

54. FDA also found the SKYTE submissions deficient for failing to include a certification statement signed by an authorized representative as required by 21 C.F.R. § 1114.7(a)(11) and 21 C.F.R. § 1114.7(m).

55. The certification statement, however, was found in the Forms 4057 that Skyte uploaded through the CTP Portal as part of the amendments on August 18, 2022.

56. The RTA order noted that “although you submitted additional submissions which may have been intended to amend your applications,” the submissions “did not specify the STNs assigned to the original submission within FDA form 4057a” in violation of 21 C.F.R. § 1114.9.

57. The RTA order states that “although your submission(s) may include the required content for a PMTA, they lack these necessary elements to accurately identify the purpose of the submission as well as the applications, products, and content which is being amended.”

58. A review of Appendix B to the RTA order, listing amendments and additional submissions received by FDA for Magellan, suggests that FDA erroneously found nine of SKYTE’s supplemental submissions from August 18, 2022, to be lacking Form 4057a-Premarket Tobacco Product Application Amendment and General Correspondence Submission.

59. The RTA order also states that the bundled PMTAs assigned STNs PM0005337 and PM0005595 contained portions that were not in English and “[w]hile they contain[ed] the original language version alongside an English translation of those portions, they do not include a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation certification statement as required by 21 C.F.R. 1114.7(b)(1).”

60. The RTA order itself states in bold that Magellan “cannot introduce or deliver for introduction” any of the ENDS products subject to the RTA order “into interstate commerce in the United States” and that doing so would be a violation of the FDCA and could result in enforcement action by FDA.

61. Penalties for selling unauthorized ENDS products can include both substantial civil penalties and criminal prosecution. 21 U.S.C. §§ 331, 333.

62. Simply resubmitting the bundled PMTAs would not provide an adequate remedy for Magellan because, to Magellan's understanding, FDA will not consider exercising enforcement discretion as to any non-tobacco-derived nicotine ENDS products unless the corresponding PMTAs were submitted by May 14, 2022, and remain pending.

F. The MDO Threatens Magellan and Vapor Train's Businesses

63. As a result of the RTA order, Vapor Train has stopped selling Magellan's Hyde-branded ENDS products and does not plan to purchase more of the products for so long as the RTA order remains in effect.

64. Vapor Train has a number of customers that regularly purchase the Hyde products subject to the RTA order from it, as well as other products, and expects that it may lose those customers' business as a result of the RTA order.

65. At the time the RTA order issued, Magellan had sold the Hyde and Juno products at issue to over 4,500 retailers nationwide.

66. Magellan had already spent over \$1 million on the PMTAs at the time the RTA order issued and plans to spend over \$10 million on the PMTAs in total.

67. Magellan's Hyde and Juno products subject to the RTA order compete with numerous other ENDS products that either have received marketing authorization from FDA or, while they also lack marketing authorization from FDA, are not subject to FDA enforcement because the PMTAs submitted by the manufacturers of those products are still pending or, if FDA has issued a marketing denial order on the application, the agency has administratively stayed or retracted the marketing denial order and is re-reviewing the application.

68. The RTA order means that Magellan thus stands to lose substantial sales to the manufacturers and distributors of these products in the highly competitive ENDS industry.

69. Even if the RTA order is stayed at a later date, because other ENDS manufacturers and distributors have not received RTA orders or other adverse actions and FDA continues to exercise enforcement discretion as to their products, Magellan will lose market share to them, as well as associated customer goodwill.

COUNT I
(Declaratory Judgment that Defendants Violated the Administrative Procedure Act)

70. Plaintiffs incorporate herein by reference the allegations set forth in paragraphs 1 through 69, above.

71. As a federal agency, FDA is subject to the requirements of the Administrative Procedure Act, including the prohibition against agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2).

72. FDA’s RTA order is a “final agency action” for which there is no other adequate remedy in a court. *See* 5 U.S.C. § 704. On November 1, 2022, the United States Court of Appeals for the Fifth Circuit held that RTA orders are not directly reviewable by it under Section 912 of the FDCA, 21 U.S.C. § 387*l*. *See* Nov. 1, 2022 Order in *Boomtown Vapor, LLC v. FDA*, Case No. 22-60467 (5th Cir. 2022).

73. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law in issuing the RTA order to Magellan.

74. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that Magellan’s applications assigned STNs PM0005337 and PM0005595 lacked translation certification statements as required by 21 C.F.R. § 1114.7(b)(1) when such translation certification statements were unnecessary because the documents at issue were original dual language documents that were already in English and so were not “[d]ocuments

that have been translated from another language into English” as specified in 21 C.F.R. § 1114.7(b)(1).

75. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that Magellan’s applications assigned STNs PM0005337; PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; and PM0006322 failed to include FDA Form 4057b—Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 C.F.R. § 1105.10(a)(6) and 21 C.F.R. § 1114.7(b) because Magellan, through its scientific advisor, submitted timely amendments that contained FDA Form 4057b for each such application prior to the issuance of the RTA order.

76. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that Magellan’s applications assigned STNs PM0005370; PM0005438; PM0005442; PM0005480; PM0005508; PM0005514; PM0005521; PM0006321; and PM0006322 failed to include a certification statement signed by an authorized representative as required by 21 C.F.R. § 1114.7(a)(11) and 21 C.F.R. § 1114.7(m) because the certification statements were found in the Forms 4057 that were submitted as timely amendments on August 18, 2022, before FDA issued the RTA order dated October 6, 2022.

77. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by failing to consider Magellan’s timely amendments submitted on August 18, 2022, on the grounds that the amendments did not include or reference the Submission Tracking Numbers assigned to the original bundled applications to which the amendments related when FDA itself failed to assign the original bundled applications corresponding Submission Tracking Numbers. FDA similarly acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the basis that Magellan’s amendments dated August 18, 2022, did not specify the STNs

assigned to the corresponding original submission within the Forms 4057a in violation 21 C.F.R. § 1114.9 and that the amendments “lack the necessary elements to accurately identify the purpose of the submission as well as the applications, products, and contents which is being amended.”

78. An actionable controversy of a justiciable nature exists between Plaintiffs and Defendants regarding whether FDA’s aforementioned conduct constitutes a violation of the Administrative Procedure Act.

79. As a direct and immediate result of FDA’s actions in violation of the requirements of the Administrative Procedure Act, Magellan and Vapor Train are suffering ongoing and irreparable harm in that the RTA order prohibits Plaintiffs from introducing or delivering Magellan’s subject ENDS products into interstate commerce. If the RTA order were stayed or vacated, Vapor Train and Magellan could return to the *status quo ante* of continuing to market the ENDS products under an exercise of FDA’s enforcement discretion while the PMTAs remained under FDA review. *See Wages & White Lion Investments, LLC v. FDA*, 16 F.4th 1130, 1143-44 (5th Cir. 2021).

WHEREFORE, Plaintiffs Magellan Technology, Inc. and Vapor Train 2 LLC request a temporary, preliminary, and permanent injunction and a declaratory judgment:

- A. Declaring that FDA acted arbitrarily, capriciously, and not in accordance with law in issuing the RTA order to Magellan;
- B. Temporarily and preliminarily staying the RTA order for the duration of this action;
- C. Setting aside FDA’s RTA order and remanding the issue back to FDA for further review of Magellan’s PMTA in accordance with law;
- D. Awarding Plaintiffs’ their reasonable attorneys’ fees, costs, and expenses under 28 U.S.C. § 2412 and other applicable authority; and

E. Granting such other and further relief as is necessary and appropriate.

Respectfully submitted,

Dated: November 3, 2022

By: /s/ G. Blake Thompson

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*Counsel for Plaintiffs Magellan Technology, Inc.
and Vapor Train 2 LLC*

VERIFICATION

I verify under penalty of perjury that the facts set forth in the foregoing complaint, other than those facts relating to Vapor Train 2 LLC, which Omar Dawud is separately verifying, are true and correct to the best of my information, knowledge, and belief.

A handwritten signature in black ink, appearing to read 'J. Glauser', is written over a horizontal line.

Mr. John Glauser
Chief Strategy Officer
Magellan Technology, Inc.

VERIFICATION

I verify under penalty of perjury that the facts set forth in the foregoing complaint relating to Vapor Train 2 LLC are true and correct to the best of my information, knowledge, and belief.

A handwritten signature in black ink, appearing to read "Omar Dawud", is written over a horizontal line.

Omar Dawud
Member
Vapor Train 2 LLC